

### Background information on Albaugh:

1. Albaugh Inc.'s Jan. 11, 1999 letter of intent to test the subject chemical (identity is CBI) under the TSCA Section 4 Dioxin/Furan (D/F) test rule was received by the TSCA Confidential Business Center (CBIC) on Jan. 19, 1999. **Their letter stated that Albaugh started importing the chemical on Nov. 16, 1998.**
2. Pyxis Regulatory Consulting, on behalf of Albaugh, submitted a "draft" protocol on 11/15/99. The draft protocol was not acceptable to EPA because it did not contain a sampling plan or a Quality Assurance Project Plan (QAPjP), and the chemical production process was not described in any detail whatsoever.
3. The "draft" protocol stated that Albaugh imports the test substance from **two separate sources** and that both sources utilize the same manufacturing process. However, the protocol stated that the samples to be tested would be obtained from only one source (i.e., the source with the greatest volume of sales and the greatest potential for exposure to intense heat and alkalinity during manufacture). EPA interprets this information regarding potential for exposure to intense heat and alkalinity during manufacture of the test substance to mean that the manufacturing process was not the same for the two sources of the chemical.
4. OPPT rejected the draft protocol with a letter signed by Dr. Sanders on 2/7/2000 and stated that EPA must review detailed production process-related information from both sources of the test substance in order to determine whether the manufacturing processes for the chemical are indeed the same, and whether testing of the chemical obtained from only one of the two sources would be adequate under the test rule. This letter also informed Albaugh that their submission was not in full compliance with the test rule and requested the company submit a revised protocol and sampling plan to EPA within 30 days.
5. EPA received Albaugh's second sampling protocol, prepared by Battelle on 3/27/2000. However, all of the information requested by EPA was not provided in the submission. In reviewing the submitted information, the Panel could not accept the extremely unorthodox sampling procedures for the product and found significant deficiencies in the analytical protocol. EPA rejected the second protocol in a letter dated 8/17/2000 and requested that Albaugh submit another protocol within 90 days. **EPA also requested the following information: "How much product is produced, the frequency of production? How much is imported, frequency of importation and the product's life cycle after the material is imported into the United States. For example, how many manufacturer's batches are imported and processed at the toll plant within a specific time frame?"** Examples of the suggested sampling strategies were provided to a company as well.
6. EPA received another protocol from Albaugh (again prepared by Battelle) on 11/24/2000.

The cover letter for this protocol dated November 21, 2000 included a request for "deferral of the requirement to conduct the testing" with the justification that Albaugh had ceased importing the test substance as of April, 2000 (a subsequent letter received by EPA via fax on 5/10/01 indicated that importation was stopped on May 12, 2000). Albaugh did not indicate the importation frequency nor the amount of chemical imported. From the sampling protocol information, EPA estimated that about 16 tons of the chemical were imported.

7. During a teleconference held on April 24, 2001, the Expert Panel did not accept this revised version of the protocol either; however, a response to the company was not sent due to their continued request for a "deferral of the requirement to conduct the testing" and additional inconsistencies in Albaugh's 5/10/01 letter stating that "...there are no remaining stocks of the Test Chemical in the United States." In the faxed letter (5/10/01), Albaugh also requested a meeting with EPA staff to discuss this matter.
8. During a meeting on 5/15/01 with OPPT, OGC, and OECA and Albaugh and its outside counsel (Douglas Green) asked again for a deferral of testing. Albaugh indicated that the final product (an herbicide) that was produced from its imported chemical was tested for dioxins and furans and that the herbicide data was submitted to EPA's OPP under FIFRA. At the meeting, the company also reported a different quantity of the imported chemical (470,000 lbs) than the company had reported previously to EPA. OPPT asked again about the existence of any retained samples, because although requested, this information was never provided to EPA. At this meeting OPPT asked for a full copy of the final report including the test data from that submitted herbicide analysis. OPPT sent a letter on May 25, 2001 to Albaugh also requesting this and other additional information.
9. In a 6/27/01 letter, Albaugh indicated that a total of 217.75 tons of the subject chemical was imported and processed between late 1998 and early 2000 from India and China.
10. Mr. Green (outside counsel for Albaugh) sent a letter to Lin Moos dated 7/02/01 again requesting a deferral from testing.
11. OPPT ( Lin Moos) replied to Doug Green's letter on August 10, 2001 and stated that testing is still required and that OPPT would communicate EPA's comments on the testing protocol directly to Albaugh in order to facilitate their testing of the subject chemical as required under the TSCA Section 4 D/F Test Rule.
12. In the summer of 2001, Senator Grassley's staff requested a meeting with OPPT to discuss a request made by a constituent (Albaugh Inc.) that the company be exempted from the DF Test Rule requirements. Dr Sanders and Dave Williams along with OECA staff attended this meeting.
13. The fourth version of the protocol for the sampling and analysis of a chemical substance



listed in 40 CFR 766.25 (EPA's TSCA Section 4 Dioxin/Furan (D/F) Test Rule) was received by EPA on January 22, 2003, and is titled "Analytical Protocol, Sampling Protocol and Quality Assurance Project Plan for the Determination of Polychlorinated Dioxins and Furans in Collected Samples of Redacted" (Battelle Study No.: AG030002) (DCN: 400330000009). The Panel finds that although the protocol has been greatly improved in the analysis sections, it is not in compliance with the applicable sections of the TSCA Section 4 Dioxins/Furans (D/F) Test Rule (40 CFR 766) for the sampling and sample selection.

- 14 The last (fifth) submission of additional information (dated January 16<sup>th</sup> 2004) was reviewed by the Panel. The Panel accepted the protocol as amended and stated that the latest version of the protocol does not need any further modifications and can be used by Albaugh for preparation and analysis of the samples obtained from batches of 2,5-dichlorophenol previously imported by Albaugh. Despite the fact that the seven samples that remain in Albaugh's possession were not collected in a manner that complies fully with the TSCA Section 4 D/F Test Rule, we believe that testing these samples will provide the Agency with valuable information regarding the potential contamination of the chemical with polychlorinated dioxins and/or furans. Therefore, it is our recommendation that we require Albaugh, Inc. to analyze these samples in accordance with the test rule. We also believe, that analysis of the existing 2,5-dichlorophenol samples will not preclude us from requiring additional testing under the D/F Test Rule if Albaugh produces or imports this chemical in the future.

	16000	16	35274
	48000	48	105822
total:	154750	154.75	341165
India	3000	3	6614
	12000	12	26455
	16000	16	35274
	16000	16	35274
	16000	16	35274
total:	63000	63	138891
both sources:		217.75	